TRAITE DE BUDAPEST SUR LA RECONNAISSANCE INTERNATIONALE DU DEPOT DES MICRO-ORGANISMES AUX FINS DE LA PROCEDURE EN MATIERE DE BREVETS

#### FORMULE INTERNATIONALE

DESTINATAIRE :

**NESTEC S.A.** Service des Brevets Avenue Nestlé 55 **1800 VEVEY** Suisse

RECEPISSE EN CAS DE DEPOT INITIAL, délivré en vertu de la règle 7.1 par 1'AUTORITE DE DEPOT INTERNATIONALE identifiée au bas de cette page

NOM ET ADRESSE DU DEPOSANT

I. IDENTIFICATION DU MICRO-ORGANISME

Référence d'identification donnée par le DEPOSANT :

**pLL112** 

Numéro d'ordre attribué par 1'AUTORITE DE DEPOT INTERNATIONALE :

I - 2089

DESCRIPTION SCIENTIFIQUE ET/OU DESIGNATION TAXONOMIQUE PROPOSEE II.

Le micro-organisme identifié sous chiffre I était accompagné :

d'une description scientifique

d'une désignation taxonomique proposée

(Cocher ce qui convient)

III. RECEPTION ET ACCEPTATION

La présente autorité de dépôt internationale accepte le micro-organisme identifié sous chiffre I, qu'elle a reçu le 04 NOVEMBRE 1998 (date du dépôt initial) I

RECEPTION D'UNE REQUETE EN CONVERSION

La présente autorité de dépôt internationale a reçu le micro-organisme identifié sous (date du dépôt initial) et a reçu une requête en conversion du dépôt initial en dépôt conforme au Traité de (date de réception de la requête en conversion)

V. AUTORITE DE DEPOT INTERNATIONALE

Nom:

CNCM

Collection Nationale de Cultures de Microorganismes

**INSTITUT PASTEUR** 28, Rue du Docteur Roux F-75724 PARIS CEDEX 15

Signature(s) de la (des) personne(s) compétente(s) pour représenter l'autorité de dépôt internationale ou de l'(des) employé(s) autorisé(s) : Mme Y. CERISIER
Directeur.Administratif de la CNCM

Date: Paris, le 14 janvier 1999

l En cas d'application de la règle 6.4.d), cette date est la date à laquelle le statut d'autorité de dépôt internationale a été acquis.

TRAITE DE BUDAPEST SUR LA RECONNAISSANCE INTERNATIONALE DU DEPOT DES MICRO-ORGANISMES AUX FINS DE LA PROCEDURE EN MATIERE DE BREVETS

#### FORMULE INTERNATIONALE

DESTINATAIRE :

NESTEC S.A. Service des Brevets Avenue Nestlé 55 1800 VEVEY Suisse RECEPISSE EN CAS DE DEPOT INITIAL, délivré en vertu de la règle 7.1 par l'AUTORITE DE DEPOT INTERNATIONALE identifiée au bas de cette page

NOM ET ADRESSE DU DEPOSANT

<ol> <li>IDENTIFICATION DU MICRO-ORGA</li> </ol>	ANTSME
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Référence d'identification donnée par le  $\mathsf{DEPOSANT}$ :

**pLL115** 

Numéro d'ordre attribué par l'AUTORITE DE DEPOT INTERNATIONALE :

1 - 2090

II. DESCRIPTION SCIENTIFIQUE ET/OU DESIGNATION TAXONOMIQUE PROPOSEE

Le micro-organisme identifié sous chiffre I était accompagné :

d'une description scientifique

a and description scientifique

d'une désignation taxonomique proposée

(Cocher ce qui convient)

III. RECEPTION ET ACCEPTATION

La présente autorité de dépôt internationale accepte le micro-organisme identifié sous chiffre I, qu'elle a reçu le 04 NOVEMBRE 1998 (date du dépôt initial) 1

IV. RECEPTION D'UNE REQUETE EN CONVERSION

La présente autorité de dépôt internationale a reçu le micro-organisme identifié sous chiffre I le (date du dépôt initial) et a reçu une requête en conversion du dépôt initial en dépôt conforme au Traité de Budapest le (date de réception de la requête en conversion)

V. AUTORITE DE DEPOT INTERNATIONALE

Nom:

**CNCM** 

Collection Nationale de Cultures de Microorganismes

Adresse :

**INSTITUT PASTEUR** 

28, Rue du Docteur Roux F-75724 PARIS CEDEX 15 Signature(s) de la (des) personne(s) compétente(s) pour représenter l'autorité de dépôt internationale ou de l'(des) employé(s) autorisé(s) : Mme Y. CERISIER Directeur, Administratif de la CNCM

Date: Paris, le 14 janvier 1999

l En cas d'application de la règle 6.4.d), cette date est la date à laquelle le statut d'autorité de dépôt internationale a été acquis.

TRAITE DE BUDAPEST SUR LA RECONNAISSANCE INTERNATIONALE DU DEPOT DES MICRO-ORGANISMES AUX FINS DE LA PROCEDURE EN MATIERE DE BREVETS

#### FORMULE INTERNATIONALE

DESTINATAIRE :

**NESTEC S.A.** Service des Brevets **Avenue Nestlé 55 1800 VEVEY** Suisse

RECEPISSE EN CAS DE DEPOT INITIAL, délivré en vertu de la règle 7.1 par 1'AUTORITE DE DEPOT INTERNATIONALE identifiée au bas de cette page

NOM ET ADRESSE DU DEPOSANT

I. IDENTIFICATION DU MICRO-ORGANISME

Référence d'identification donnée par le DEPOSANT :

**pLL116** 

Numéro d'ordre attribué par 1'AUTORITE DE DEPOT INTERNATIONALE :

i - 2091

II. DESCRIPTION SCIENTIFIQUE ET/OU DESIGNATION TAXONOMIQUE PROPOSEE

Le micro-organisme identifié sous chiffre I était accompagné :

d'une description scientifique

d'une désignation taxonomique proposée

(Cocher ce qui convient) .

III. RECEPTION ET ACCEPTATION

La présente autorité de dépôt internationale accepte le micro-organisme identifié sous chiffre I, qu'elle a reçu le 04 NOVEMBRE 1998 (date du dépôt initial) 1

IV. RECEPTION D'UNE REQUETE EN CONVERSION

La présente autorité de dépôt internationale a reçu le micro-organisme identifié sous chiffre I le (date du dépôt initial) et a reçu une requête en conversion du dépôt initial en dépôt conforme au Traité de Budapest le (date de réception de la requête en conversion)

V. AUTORITE DE DEPOT INTERNATIONALE

Nom:

CNCM

Collection Nationale de Cultures de Microorganismes

Adresse :

**INSTITUT PASTEUR** 

28, Rue du Docteur Roux F-75724 PARIS CEDEX 15

Signature(s) de la (des) personne(s) compétente(s) pour représenter l'autorité de dépôt internationale ou de l'(des) employé(s) autorisé(s) : Mme Y. CERISIER
Directeur Administratif de la CNCM

Date: Paris, le 14 ianvier 1999

l En cas d'application de la règle 6.4.d), cette date est la date à laquelle le statut d'autorité de dépôt internationale a été acquis.

## TENT COOPERATION TRE.

To:

#### From the INTERNATIONAL BUREAU

#### **PCT**

#### **NOTIFICATION OF ELECTION**

(PCT Rule 61.2)

Commissioner **US Department of Commerce** United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24

Arlington, VA 22202 **ETATS-UNIS D'AMERIQUE** 

in its capacity as elected Office

Date of mailing (day/month/year) 21 February 2001 (21.02.01)

International application No. PCT/EP00/05834

International filing date (day/month/year)

23 June 2000 (23.06.00)

Applicant's or agent's file reference

80197/WO

Priority date (day/month/year) 30 June 1999 (30.06.99)

**Applicant** 

GERMOND, Jacques, Edouard et al

ł	
1.	The designated Office is hereby notified of its election made:
	X in the demand filed with the International Preliminary Examining Authority on:
	08 January 2001 (08.01.01)
	in a notice effecting later election filed with the International Bureau on:
2.	The election X was
	was not
	made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland

Authorized officer

R. E. Stoffel

Telephone No.: (41-22) 338.83.38

Facsimile No.: (41-22) 740.14.35



## **PCT**

REC'D 1 2 NOV 2001

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applican	it's or a	agent's file reference		
80197/	wo		FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
1		pplication No.	International filing date (day/month/	/year) Priority date (day/month/year)
PCT/E	P00/0	05834	23/06/2000	30/06/1999
C12N1 Applicant	5/31	atent Classification (IPC) or na	tional classification and IPC	
SOCIE	TE D	ES PRODUITS NESTLE	S.A. et al.	
1. This and	inter is tra	national preliminary examii nsmitted to the applicant ad	nation report has been prepared locording to Article 36.	by this International Preliminary Examining Authority
2. This	REP	ORT consists of a total of	5 sheets, including this cover she	eet.
		arriorided and are the basis	by ANNEXES, i.e. sheets of the s for this report and/or sheets cor 7 of the Administrative Instruction	description, claims and/or drawings which have ntaining rectifications made before this Authority s under the PCT).
Thes	se anr	nexes consist of a total of 2	? sheets.	
3. This	report	contains indications relati	ng to the following items:	:
t	$\boxtimes$	Basis of the report		
H		Priority		
Ш		Non-establishment of opin	nion with regard to novelty, inven	tive step and industrial applicability
IV		Lack of unity of invention	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	and modestral applicability
V	☒	Reasoned statement und citations and explanations	er Article 35(2) with regard to noves suporting such statement	velty, inventive step or industrial applicability;
VI		Certain documents cited		
VII		Certain defects in the inte		
VIII	⊠	Certain observations on the	ne international application	
Date of subi	missio	n of the demand	Date of com	pletion of this report
08/01/200	)1		05.11.2001	
lame and m reliminary e	examin	address of the international ing authority:	Authorized o	fficer Succes More
<u>)</u> ))	D-802 Tel. +	ean Patent Office 298 Munich 49 89 2399 - 0 Tx: 523656 epi	Barnas, C	
-	Fax: +	-49 89 2399 - 4465	Tolophoro	2 . 40 00 0000 Tues

#### INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

International application No. PCT/EP00/05834

I.	Basis	of the	ereport
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	ti a	ne receiving Office ir	ements of the international response to an invitation to this report since they do	under Article 14 are	referred to in this	report as "originally filed"
	1	-28	as originally filed			
	С	laims, No.:				
	6-	15	as originally filed			
	1-	5,16,17	as received on	04/10/2001	with letter of	04/10/2001
	Di	rawings, sheets:				
	1-	9	as originally filed			
	Se	equence listing par	t of the description, page	es:		
	1-7	7, as originally filed				
2.	. Wi lar	th regard to the <b>lang</b> guage in which the	guage, all the elements ma international application w	arked above were avas filed, unless othe	vailable or furnishe rwise indicated un	d to this Authority in the der this item.
	Th	ese elements were a	available or furnished to th	is Authority in the fo	llowing language:	, which is:
			translation furnished for th			(under Rule 23.1(b)).
			ublication of the internation			
		the language of a to 55.2 and/or 55.3).	translation furnished for th	e purposes of intern	ational préliminary	examination (under Rule
3.	Wit	h regard to any <b>nuc</b> ernational preliminar	leotide and/or amino acion was carried	d sequence disclosed out on the basis of the	ed in the internatio the sequence listin	nal application, the g:
	$\boxtimes$	contained in the int	ternational application in w	ritten form.		
	$\boxtimes$		the international application		ble form	
			ently to this Authority in wr			
			ently to this Authority in co		m.	•
		The statement that	the subsequently furnished	ed written sequence		beyond the disclosure in
			the information recorded i		e form is identical t	o the written sequence
					i	

3.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/05834

listing has been furnished. 4. The amendments have resulted in the cancellation of: ☐ the description, pages: ☐ the claims, Nos.: ☐ the drawings, sheets: 5. 

This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)): (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.) 6. Additional observations, if necessary: V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement 1. Statement Novelty (N) Yes: Claims 1-17 No: Claims Inventive step (IS) Yes: Claims 1-17 No: Claims Industrial applicability (IA) Yes: Claims 1-17 No: Claims

2. Citations and explanations see separate sheet

### VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made: see separate sheet

#### **EXAMINATION REPORT - SEPARATE SHEET**

#### Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

D1: EP-A-0 643 137 (NESTLE SA) 15 March 1995 (1995-03-15)

#### Arts. 33(2)(3) PCT, Novelty and Inventive Step

- The present set of claims which refers to the lac operon of Lactobacillus delbrueckii 1. subsp. lactis or to subregions of said operon is new over the cited prior art.
- D1 represents the closest prior art for the subject matter of the present application. 2. Said document discloses a DNA sequence containing gene of interest (chloramphenicol acetyltransferase) under the control of the lac promoter/operator of L. delbrueckii bulgaricus (p. 4, ln. 16-25 and Fig. 5). Said DNA does not contain a lac repressor protein.
- The difference between D1 and the present application is the isolation of the lac 3. operon of Lactobacillus delbrueckii lactis and its use for the expression of heterologous genes of interest. The cited prior art does not contain any indication that would prompt the skilled person to isolate said operon. The present set of claims which refers to said operon or to subregions of said operon is, therefore, inventive.

#### Re Item VIII

## Certain observations on the international application

- SEQ ID NO: 9 is the lac promoter/operator of L. delbrueckii lactis. Said DNA sequence binds to the lac repressor protein of L. delbrueckii lactis. The subsentence "... which retains its capability to bind ... of L. delbrueckii..." in claim 1 is, therefore, an undue repetition of an inherent capability of SEQ ID NO: 9. In addition, SEQ ID NO: 9 only binds to the repressor of Lactobacillus delbrueckii lactis not of Lactobacillus delbrueckii bulgaricus. The latter is, however, embraced by the term Lactobacillus delbrueckii. Claim 1 is, therefore, neither concise nor clear (Art. 6 PCT).
- Claim 6 states that the DNA of the proceeding claims should be devoid of 2. catabolite responsive elements. "Catabolite responsive elements" is however, only an

## INTERNATIONAL PRELIMINARY International application No. PCT/EP00/05834 EXAMINATION REPORT - SEPARATE SHEET

alternative expression for "lac repressor" in the context of the present application. DNAs which are devoid of such elements/repressors are, however, already described in claim 1 ("R<sub>y</sub> wherein Y is 0 or 1"). Claim 6, therefore, unduly describes the same subject matter which is already described in claim 1. The present set of claims is, therefore, also because of this reason not concise (Art. 6 PCT).

### Amended Claims

1. A DNA sequence represented by the following general formula

$$p/o - (A)_n - R_y$$
, or  $p/o - R_y - (A)_n$ 

wherein

p/o denotes the DNA sequence identified under SEQ ID No. 9 pr a functional variant thereof, which retains its capability to bind to the lac repressor protein of Lactobacillus delbrueckii;

A denotes a gene coding for a polypeptide of interest,

n denotes an integer of  $\geq 0$ ;

R denotes a gene coding for the lac repressor protein as identified under SEQ ID No.

2 pr a functional variant thereo; and

Y is 0 or 1.

- 2. The DNA sequence according to claim 1, wherein y is 1.
- 3. The DNA sequence according to claim 1, wherein the reading frame of gene coding for the lac repressor is reversed relative to the region p/o.
- 4. The DNA sequence according to claim 1 wherein the gene coding for a polypeptide of interest is selected from group consisting of genes encoding enzymes, cell surface proteins, or functional peptides.
- 5. The DNA sequence according to claim 4, wherein the gene coding for a polypeptide of interest is selected from the group consisting of genes coding for dextransucrase, glycosyltransferase, phytase, transglutaminase, peptidase, phenylalanine ammonia lyase, protease, cell surface antigens, bacteriocins, hormones or insulin.

- 16. The use according to any of the claims 13 to 15, wherein expression is performed in microorganisms selected from the group consisting of lactic acid bacteria.
- 17. The use of a microorganism according to any of the claims 8 to 11 for the production of food products.



(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	I OH UH HEH OUT TOUNDARION	of Transmittal of International Search Report
80197/WO	ACTION (Form PCT/ISA/	220) as well as, where applicable, item 5 below.
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/EP 00/05834	23/06/2000	30/06/1999
Applicant	20,00,200	30/00/1999
SOCIETE DES PRODUITS	NESTLE S.A.	
This International Search Report haccording to Article 18. A copy is b	as been prepared by this International Searching Aut eing transmitted to the International Bureau.	hority and is transmitted to the applicant
This International Search Report c	onsists of a total of3 sheets.  nied by a copy of each prior art document cited in this	report.
Basis of the report		
a. With regard to the language	ge, the international search was carried out on the based, unless otherwise indicated under this item.	sis of the international application in the
, ,		
b. With regard to any nucleot was carried out on the basi	ide and/or amino acid sequence disclosed in the in soft the sequence listing:	ternational application, the international search
	ernational application in written form.	
	he international application in computer readable form	1.
	ently to this Authority in written form.	,
	ently to this Authority in computer readble form.	
the statement that t	he subsequently furnished written sequence listing do ation as filed has been furnished.	pes not go beyond the disclosure in the
	he information recorded in computer readable form is	identical to the written sequence listing has been
2. Certain claims wer	e found unsearchable (See Box I).	
	is lacking (see Box II).	
4. With regard to the <b>title</b> ,		
X the text is approved	as submitted by the applicant.	
	tablished by this Authority to read as follows:	
. With regard to the abstract.		
om '	as submitted by the applicant.	
the text has been es	as submitted by the applicant. tablished, according to Rule 38.2(b), by this Authority m the date of mailing of this international search repo	as it appears in Box III. The applicant may,
The Control of the Co	published with the abstract is Figure No.	5
The figure of the drawings to be	in the about dot is I idule IVO.	
The figure of the <b>drawings</b> to be  as suggested by the		None of the figures
as suggested by the		None of the figures.

ernational Application No PCT/EP 00/05834

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C12N15/31 C12N15/74

C07K14/335

A23C9/123

According to International Patent Classification (IPC) or to both national classification and IPC

#### B. FIELDS SEARCHED

 $\begin{array}{ccc} \text{Minimum documentation searched} & \text{(classification system followed by classification symbols)} \\ IPC 7 & C12N & C07K & A23C \end{array}$ 

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, STRAND

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 643 137 A (NESTLE SA) 15 March 1995 (1995-03-15)	1,4-6, 8-11,
	SEQ ID NO 2	13-17
Υ	page 4, line 17 - line 25 page 5, line 1 - line 13 page 20 -page 22	2,3
Y A	WO 93 17117 A (LYNXVALE LTD) 2 September 1993 (1993-09-02) page 1, line 23 - line 26	2,3 1,4, 6-11,
	page 17, line 13 -page 18, line 2; figure	13-17
	page 21, line 10 - line 24	
	-/	

V Further decuments and links to the	
Y Further documents are listed in the continuation of box C.	χ Patent family members are listed in annex.
° Special categories of cited documents :	
"A" document defining the general state of the art which is not considered to be of particular relevance  "E" earlier document but published on or after the international filing date  "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  "O" document referring to an oral disclosure, use, exhibition or other means  "P" document published prior to the international filing date but later than the priority date claimed	<ul> <li>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</li> <li>"&amp;" document member of the same patent family</li> </ul>
Date of the actual completion of the international search	Date of mailing of the international search report
3 November 2000	09/11/2000
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk	Authorized officer
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	van Klompenburg, W

rnational Application No

C.(Continua	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	TCT/EP 00/05834
Category °		
	passages	Relevant to claim No.
<b>X</b>	LEONG-MORGENTHALER P ET AL: "LACTOSE METABOLISM IN LACTOBACILLUS BULGARICUS: ANALYSIS OF THE PRIMARY STRUCTURE AND EXPRESSION OF THE GENES INVOLVED" JOURNAL OF BACTERIOLOGY, vol. 173, no. 6, 1 March 1991 (1991-03-01), pages 1951-1957, XP000749822 ISSN: 0021-9193 page 1953; figure 3	1,4,6, 8-11, 13-16
	US 5 676 985 A (WU YALING ET AL) 14 October 1997 (1997-10-14)  column 2, line 52 - line 58 column 3, line 5 - line 12 column 5, line 27 - line 35 column 7, line 33 -column 8, line 10; claim 5	1,4,6, 8-11, 13-17
	DUBENDORFF J W ET AL: "CONTROLLING BASAL EXPRESSION IN AN INDUCIBLE T7 EXPRESSION SYSTEM BY BLOCKING THE TARGET T7 PROMOTER WITH LAC REPRESSOR" JOURNAL OF MOLECULAR BIOLOGY, vol. 219, no. 1, 1 January 1991 (1991-01-01), pages 45-59, XP000605448 ISSN: 0022-2836 figures 3,9	2,3,7
	AJDIC ET AL.: "Organization and nucleotide sequence of the Streptococcus mutans galactose operon" EMBL ACC NO U21942, vol. 180, 18 March 1997 (1997-03-18), pages 137-144, XP002121893 the whole document -& AJDIC ET AL.: "Organization and nucleotide sequence of the Streptococcus mutans galactose operon" GENE, vol. 180, 1996, pages 137-144, XP002122211 figure 1	7

ation on patent family members

T/EP 00/05834

Patent document cited in search report		Publication Patent fa		atent family Publication		
		date		member(s)	date	
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				BR	9403325 A	11-04-1995
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				AU	3602395 A	06-05-1996
				CA	2202373 A	25-04-1996
				WO	9611586 A	25-04-1996
				DE	69509669 D	17-06-1999
				DE	69509669 T	21-10-1999
				DK	785727 T	29-11-1999
				EP	0785727 A	30-07-1997
				ES	2132713 T	16-08-1999
				GR	3030928 T	30-11-1999
				JP	10509304 T	14-09-1998